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In The

Supreme Court of the United States

UNITED STATES,

Petitioner,

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE, ET AL.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF THE INSTITUTE ON GLOBAL DRUG POLICY OF THE DRUG FREE AMERICA FOUNDATION; NATIONAL FAMILIES IN ACTION; DRUG WATCH INTERNATIONAL; DRUG-FREE KIDS: AMERICA'S CHALLENGE, ET AL., AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether crude marijuana is a safe and effective medicine that should be available for medical purposes and be removed from Schedule I as a controlled dangerous substance?

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INTEREST OF AMICI AND SUMMARY OF ARGUMENT[1]

Amici are nonprofit corporations and individuals who are concerned with preventing drug abuse. The names of amici are: America Cares, Inc., Maryland; Arizonans for Drug-Free Youth and Communities, Arizona; CEDRO Centro de Informacion y Education para La Prevencion del Abuso de Drogas, Peru; Center for Drug Information, Illinois; Christian Drug Education Center, Colorado; Committees of Correspondence, Massachusetts; Community Anti-Drug Coalitions of America, Virginia; Concerned Citizens for Drug Prevention, Massachusetts; Drug Abuse Resistance Education (DARE), California; Drug Free America Foundation, Florida; Drug Free Kids: America's Challenge, Kentucky; Drug Prevention Network of the Americas, Texas; Drug Watch International, Nebraska; Drug Watch Minnesota, Minnesota; Educating Voices, Illinois; Hippokratic Society, Austria; Institute for Behavior and Health, Inc., Maryland; Institute on Global Drug Policy of the Drug Free America Foundation, Florida; International Drug Strategy Institute, Washington; International Scientific and Medical Forum on Drug Abuse, Florida; International Students in Action, California; Main South Alliance for Public Safety, Massachusetts; Maryland Alliance for Drug-Free Youth, Maryland; National Drug Prevention Alliance of the United Kingdom, United Kingdom; National Families in

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[1] The parties have consented to the filing of this brief. (See Appendix A.) Counsel for a party did not author this brief in whole or in part. No person or entity, other than the *Amicus Curiae*, its members, or its counsel made a monetary contribution to the preparation and submission of this brief.

Action, Georgia; National Family Partnership, Florida; National Institute of Citizen Anti-Drug Policy, Virginia; National Coalition, Maryland; New Jersey Federation for Drug-Free Communities, New Jersey; Northwest Center for Health and Safety, Oregon; Parents Association to Neutralize Drug and Alcohol Abuse, Virginia; Positive Moves: Creating A Safe and Healthy World, Pennsylvania; PRIDE Omaha, Nebraska; S.O.S. Save Our Society From Drugs, Florida; Westminster Area Community Awareness Action Team, Colorado; Washington Drug-Free Business Initiative, Washington; Ernst Aeschbach, M.D., Switzerland; Mary Brett, England; Robert Dupont, M.D., former director, National Institute on Drug Abuse, Maryland; Drew Edwards, M.S., Florida; Stephanie Haynes, Texas; Janet Lapey, M.D., Massachusetts; Carla Lowe, California; Ambassador Mel Levitsky, former Assistant Secretary of State for International Narcotics Matters, New York; Ashraf Mozayani, Ph.D., Texas; Mina Seinfeld de Carakushansky, Ph.D., Drug Prevention Bureau of the City of Rio de Janeiro; Harold E. Shinitzky, Psy. D., Florida; Richard Schwartz, M.D., Virginia; and Raymond Scalettar, M.D., Washington D.C.

Amici are parents, parent and other drug-prevention organizations, and distinguished medical and scientific experts, policy makers, and others who all share a common concern that smoked or crude marijuana is disingenuously referred to as medicine. The international makeup of Amici reflects the international concern that illicit drug use is undercutting traditional values and threatening the very existence of stable families, communities, and government institutions throughout the world.

Amici collectively support families, communities, and nations that are free of illicit drug use, drug abuse, drug addiction, and drug-related deaths through advocacy and solid medical and scientific research and oppose the de jure and de facto legalization of marijuana and all other current illicit drugs. Smoked or "crude" marijuana is a dangerous Schedule I drug, notwithstanding creative attempts by those who seek its legalization to label its use as "compassionate" in medical settings. Lastly, medical marijuana initiatives now in law in eight states and the district of Columbia undermine national drug-enforcement priorities and our well-designed federal system of approval of new drugs. While future use of the state ballot initiative process as a tool to replace the legislative process must be dealt with by state legislatures, ultimately the federal government and courts must address this important issue to ensure a consistently applied and clearly understood national drug policy, as well as to preserve the Food and Drug Administration's medical and scientific new drug approval process that protects Americans from unsafe, ineffective drugs.

ARGUMENT

THE GOVERNMENT HAS A STRONG INTEREST IN PREVENTING THE DISTRIBUTION OF CRUDE MARIJUANA* UNDER CALIFORNIA'S PROPOSITION 215 WHICH VIOLATES FEDERAL LAW BECAUSE THE FOOD AND DRUG ADMINISTRATION HAS NOT APPROVED CRUDE MARIJUANA AS A SAFE OR EFFECTIVE MEDICINE AND IT IS A CONTROLLED SCHEDULE I DRUG

In *United States v. Oakland Cannabis Buyers' Cooperative*, 190 F.3d 1109 (9th Cir. 1999), the court reversed and remanded the District Court's decision granting the United States a preliminary injunction halting the distribution of crude marijuana for medical use by the Oakland Cannabis Buyers' Cooperative (the "OCBC") in the wake of Proposition 215, California's initiative legalizing medical use of crude marijuana. *Id.* at 1115. The District Court entered a preliminary injunction to stop the distribution of cannabis and held that the distribution of crude marijuana by certain cannabis clubs and their agents likely violated the Comprehensive Drug Abuse Prevention and

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* Throughout this brief we use the term "crude marijuana" to describe the illicit Schedule I drug that people abuse. The drug is derived from the leaves and flowering tops of the Cannabis plant and is consumed in a variety of ways. The dried plant material is most often rolled in paper and smoked as a cigarette, called a "joint." It is often placed in smoking devices called "bongs," smoked in pipes, or smoked in "blunts," which are cigars from which the tobacco has been removed and replaced with marijuana plant material. Sometimes it is baked in cookies or brownies and eaten, or brewed in tea and drunk. Other methods for consuming the drug are constantly being developed by the drug culture, including versions that allegedly aerosolize crude marijuana to remove its "tars."

Control Act of 1970 (the "Controlled Substances Act"), 21 U.S.C. § 841(a)(1). In reversing the District Court's decision, the Ninth Circuit stated that:

> In short, the OCBC had presented evidence that there is a class of people with serious medical conditions for whom the use of cannabis is necessary in order to treat or alleviate those conditions or their symptoms; who will suffer serious harm if they are denied cannabis; and for whom there is no legal alternative to cannabis for the effective treatment of their medical conditions because they have tried other alternatives and have found that they are ineffective, or that they result in intolerable side effects.
>
> The government, by contrast, has yet to identify *any* interest it may have in blocking the distribution of cannabis to those with medical needs, relying exclusively on its general interest in enforcing its statutes. *It has offered no evidence to rebut OCBC's evidence that cannabis is the only effective treatment for a large group of seriously ill individuals.* . . .

Id. at 1115 (emphasis added).

There is a strong governmental interest in prohibiting the distribution of crude marijuana as medicine. The federal government strives to protect our citizens from unsafe, ineffective substances sold as "medicines" and from drug abuse, drug addiction, and the abusive and criminal behaviors that marijuana and other illicit drugs often generate. The OCBC is distributing an unproven drug in disregard of the government's objective to ensure the safety and efficacy of medicines.

Because the OCBC is basing its right to procure and sell crude marijuana as "medicine," the drug must first be approved by the Food and Drug Administration (the "FDA"). The federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 351-360 gives the federal government sole responsibility for determining that drugs are safe and effective, a requirement all medicines must meet before they may be distributed to the public. The FDA has not approved marijuana as safe or effective, so the drug may not legally be prescribed and sold as a medicine. *See id.*

Not only has the FDA failed to approve marijuana, but marijuana is a Schedule I controlled substance under the Controlled Substances Act. Schedule I drugs have "1) a high potential for abuse, 2) no currently accepted treatment in the United States, and 3) a lack of accepted safety for use of the drug . . . under medical supervision." 21 U.S.C. § 812(b)(f).

In *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.D.C. 1994), the United States District Court for the District of Columbia accepted the Drug Enforcement Administration's new five-part test for determining whether a drug is in "currently accepted medical use." *Id.* at 1135. The test requires that:

(1) The drug's chemistry must be known and reproducible;

(2) there must be adequate safety studies;

(3) there must be adequate and well-controlled studies proving efficacy;

(4) the drug must be accepted by qualified experts; and

(5) the scientific evidence must be widely available.

Applying these criteria to a petition to reschedule crude marijuana, the court found that the drug had no currently accepted medical use and, therefore, had to remain in Schedule I. Thus, the OCBC disregarded the FDA's statutorily prescribed mandate created to ensure drug safety and is distributing an untested, unsafe Schedule I drug in violation of the Controlled Substances Act.

In reversing the District Court's decision, the Ninth Circuit also held that the District Court erred in failing to consider the criteria for a medical necessity exemption established by the Ninth Circuit in *United States v. Aguilar*, 883 F.2d 662, 692 (9th Cir.1989). In *Aguilar* the court held that a defendant must establish the existence of four elements to be entitled to a necessity defense: (1) that he was faced with a choice of evils and chose the lesser evil; (2) that he acted to prevent imminent harm; (3) that he reasonably anticipated a causal relation between his conduct and the harm to be avoided; and (4) that there were no other legal alternatives to violating the law. *Id.* at 693.

The OCBC does not meet the *Aguilar* requirements because it fails to satisfy at least the first and fourth elements of the test. Although the FDA has not approved crude marijuana as safe and effective, the FDA *has* approved medications to treat all of the diseases, symptoms, and ailments named in Proposition 215. The OCBC is incorrect when it asserts that it was entitled to the necessity defense under *Aguilar* because it had no other legal alternatives to violating the law. Because safe and effective legal alternatives to crude marijuana exist, the OCBC can not satisfy the *Aguilar* test and, therefore,

cannot distribute marijuana as a medicine absent the approval of the FDA.

ADVOCATES HAVE TRIED TO LEGALIZE MARIJUANA IN ONE FORM OR ANOTHER FOR THREE DECADES

Drug-legalization advocates over the last three decades have employed a number of political and legal strategies to legalize marijuana. Between 1972 and 1978, the National Organization for the Reform of Marijuana Laws (NORML) successfully lobbied eleven state legislatures to "decriminalize" the drug, reducing penalties for possession in most cases to that of a traffic ticket. Also in 1972, NORML began the first of several unsuccessful attempts to petition the Drug Enforcement Administration (DEA) to reschedule marijuana from Schedule I to Schedule II on the grounds that crude marijuana had putative use in medicine. These attempts failed. See, *National Org. for the Reform of Marijuana Laws v. Ingersoll*, 497 F.2d 654 (D.C. Cir. 1974); *National Org. for the Reform of Marijuana Laws v. Drug Enforcement Admin.*, 559 F.2d 735 (D.C. Cir. 1977); *National Org. for the Reform of Marijuana Laws v. Drug Enforcement Admin. & Dept. of Health, Education & Welfare*, No. 79-1660, 1980 U.S. App. LEXIS 13099 (D.C. Cir. Oct. 16, 1980); and *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994).

NORML and others led a second lobbying campaign aimed at states in the 1980s, this time to legalize crude marijuana as medicine. Some 35 states passed such laws but, because these laws were written by state legislative counsels and stayed within the framework of federal law, establishing statewide research programs under FDA

guidelines, advocates failed to get what they wanted – freely available marijuana.

In the early 1990s, NORML, the Drug Policy Foundation (DPF), and The Lindesmith Center (TLC) renewed the effort to legalize crude marijuana as medicine, this time using the state ballot initiative process, a process that allowed advocates to circumvent state legislative counsels and write their own laws. NORML, DPF, and TLC persuaded their most generous funders to create political organizations – Californians for Medical Rights and Arizonans for Drug Policy Reform – and to finance the first two medical marijuana initiatives in California and Arizona in 1996 and all subsequent initiatives that have passed since then. After the first two initiatives, Californians for Medical Rights became Americans for Medical Rights (AMR), which led successful medical marijuana initiative campaigns in 1998 in Alaska, Colorado, Nevada, Oregon, and Washington and in 1999 in Maine (Table 1). Different sponsors succeeded in passing a medical marijuana initiative in the District of Columbia 1998, with assistance from AMR.

Proposition 215, the state law under which the OCBC claims the right to obtain and sell cannabis, legalizes crude marijuana for "the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, *or any other illness for which marijuana provides relief*" (emphasis added). After the proposition passed, its author told the press that *anyone* who uses marijuana is "self-medicating" and that therefore *all* marijuana use is for medical purposes. "The Return of Pot", Hanna Rosin, *The New Republic*, February 17, 1997.

THE FACT THAT ONE CHEMICAL IN MARIJUANA IS AN FDA-APPROVED MEDICINE DOES NOT MAKE CRUDE MARIJUANA AN APPROVED MEDICINE

Crude marijuana is derived from the leaves and flowering tops of the Cannabis plant. It contains some 400 chemicals, most of which have not been studied by scientists. Some 60 of these chemicals, called cannabinoids, are unique to the Cannabis plant. One cannabinoid, Delta-9-tetrahydrocannabinol (THC), was synthesized, tested, and approved by FDA in 1985 for treating nausea in cancer patients and wasting in AIDS patients. The drug's generic name is dronabinol and its trade name is Marinol[R]. It is produced by Unimed Pharmaceuticals.

According to John A. Benson, Jr., M.D., of the Institute of Medicine, research on other cannabinoids is underway and some of these chemicals may one day prove to be useful medicines. However, he states:

> While we see a future in the development of chemically defined cannabinoid drugs, we see little future in smoked marijuana as a medicine.[2]

The fact that crude marijuana contains a chemical that has been synthesized, tested, and approved for medical use does not make marijuana itself a safe or effective medicine. Modern pharmaceutical science would require all the 400 or more chemicals in marijuana to pass the safety and efficacy tests in research, and this has not happened. Any consideration of this issue must take into account the substantial toxicity and morbidity associated

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[2] John A. Benson, Jr., Co-Principal Investigator, in releasing *Marijuana and Medicine: Assessing the Science Base*, Institute of Medicine, National Academy of Sciences, 1999.

with marijuana use. Because of the impurity of crude marijuana and its known toxic effects, it does not represent a useful medical alternative to currently available medications. Furthermore, efforts to gain legal status of marijuana through ballot initiatives seriously threaten the Food and Drug Administration process of proving safety and efficacy, and they create an atmosphere of medicine by popular vote, rather than the rigorous scientific and medical process that all medicines must undergo.

Before the development of modern pharmaceutical science, the field of medicine was fraught with potions and herbal remedies. Many of those were absolutely useless, or conversely were harmful to unsuspecting subjects. Thus evolved our current Food and Drug Administration and drug scheduling processes, which should not be undermined.

Having extensively reviewed available therapies for chemotherapy-associated nausea, glaucoma, multiple sclerosis, and appetite stimulation,[3] Drs. Voth and Schwartz have determined that no compelling need exists to make crude marijuana available as a medicine for physicians to prescribe. They concluded that the most appropriate direction for THC research is to research specific cannabinoids or synthetic analogs rather than pursuing the smoking of marijuana.

The conclusions of Drs. Voth and Schwartz were echoed a year later by the National Academy of Science's

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[3] Voth, E. A., Schwartz, R. H., Medicinal Applications of Delta-9-Tetrahydrocannabinol and Marijuana. *Annals of Internal Medicine*. 1997;126:791-798.

Institute of Medicine (herinafter "IOM Report") in an assessment of scientific marijuana and cannabinoid research (see below).[4]

Available research on the utility of THC has demonstrated some effectiveness of the purified form of the drug in treating nausea associated with cancer chemotherapy. Examples of such research include Sallan, et al.[5] who dealt only with pure THC in the treatment of chemotherapy-associated nausea, not smoked marijuana. Chang[6] tested THC and then followed treatment failures with marijuana, thus conclusions regarding effectiveness cannot be readily attributed to either THC or crude marijuana. Levitt[7] and coworkers actually determined that purified THC was more effective than smoked marijuana. Vinciguerra[8] found that smoked marijuana controlled

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[4] *Marijuana and Medicine: Assessing the Science Base.* Janet E. Joy, Stanley J. Watson, Jr., and John A. Benson, Jr., Editors. Division of Neuroscience and Behavioral Health. Institute of Medicine, National Academy of Sciences. National Academy Press, Washington D.C., 1999.

[5] Sallan, S. S., et al., Antiemetics effects of delta-9-tetrahydrocannabinol in patients receiving cancer chemotherapy. *NEJM.* 1975;293:795-797.

[6] Chang, et al., Delta-9-tetrahydrocannabinol as an antiemetic in cancer patients receiving high-dose methotrexate. *Annals of Internal Medicine.* 1979;91:819-924.

[7] Levitt, et al., Randomized double blind comparison of delta-9-tetrahydrocannibinol and marijuana as chemotherapy antiemetics. *Proceedings of the Annual Meeting of the American Society of Clinical Oncology.* 1984:91.

[8] Vinciguerra, V., Moore, T., Brennan, E.: Inhalation marijuana as an antiemetic for cancer chemotherapy. *N.Y. State J. Med.* 1988; 88:525-527.

nausea in patients who had failed other conventional forms of antiemetic therapy. Responders tended to have had prior marijuana experience. This study was uncontrolled and patients self-evaluated results. Smokers were required to inhale deeply, hold the smoke for ten seconds, and then smoke four cigarettes completely each day of chemotherapy. Twenty-five percent refused to smoke the marijuana. Over 20% of the subjects dropped out of the smoking group prior to the end of the study and 22% of the remaining subjects reported no benefit from smoking marijuana. Dosing was also variable because of the fact that the dose was rounded to the nearest one-fourth marijuana cigarette, and no THC levels were checked for consistency of dose response.

Legalization advocates would have the public and policy makers incorrectly believe that crude marijuana is the only treatment alternative for masses of cancer sufferers who are going untreated for the nausea associated with chemotherapy, and for all those who suffer from glaucoma, multiple sclerosis, and other ailments. Numerous effective medications are, however, currently available for conditions such as nausea (Table 2).

In fact, the IOM report found that neither smoked marijuana nor cannabinoids are as effective as current medicines that stop nausea and vomiting in cancer chemotherapy patients. However, the scientists speculated that cannabinoids might be effective in those few patients who respond poorly to current antiemetic (anti-nausea) drugs or more effective in combination with current antiemetics. It recommended that research should be pursued for patients who do not respond completely to current

antiemetics and that a safe (non-smoking) delivery system *for cannabinoids should be developed.*

The negative side effect profile for marijuana, even oral dronabinol (Marinol[R]), far exceeds most of the other effective agents available. *If* there exist treatment failures of available medications in these patients, the use of marijuana would, at minimum, demonstrate unpleasant side effects. In the studies performed to examine THC for chemotherapy-associated nausea, elderly patients could not tolerate the drug. Chronic, daily doses of the drug would be necessary to treat many of the proposed medical conditions. This would unnecessarily expose the patients to the toxic effects.

Mattes[9] compared oral and rectal suppository preparations of THC with smoked marijuana. All study subjects were experienced marijuana users thus accounting for a relatively high drug acceptance. Smoked marijuana was no more effective than suppository THC in stimulating appetite as measured by caloric energy intake. Rectal suppositories and oral THC were dosed at 2.5 mg twice daily. Marijuana subjects were required to inhale for 3 seconds, hold the smoke deeply in their lungs for 12 seconds, and then continue the process until the cigarette was smoked to a stub. The plasma THC levels peaked more quickly with the inhaled THC, but also fell more quickly, whereas the suppository THC maintained a more sustained level.

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[9] Mattes, R. D., Engelman, K., Shaw, L. M., Elsohly, M. A., Cannabinoids and appetite stimulation. *Pharmacologic Pharmacology, Biochemistry, and Behavior.* 1994;49:187-195.

To examine the potential medical efficacy of marijuana as it relates to several disease states, a comprehensive review of the potential medicinal applications of marijuana was recently undertaken at the request of the Assistant Secretary of Health, Dr. Phillip Lee. Opinions were requested from investigators at the National Institute on Allergy and Infectious Diseases, who commented on the AIDS wasting syndrome; the National Cancer Institute who commented on the use of marijuana as an antiemetic in cancer chemotherapy; the National Eye Institute who commented on marijuana's use in glaucoma; and the National Institute for Neurological Disorders and Stroke who commented on marijuana's role as an antispasticity drug in multiple sclerosis. The summary opinion stated:

> This evaluation indicates that sound scientific studies supporting these claims are lacking despite anecdotal claims that smoked marijuana is beneficial. Scientists at the National Institutes of Health indicate that after carefully examining the existing preclinical and human data, there is no evidence to suggest that smoked marijuana might be superior to currently available therapies for glaucoma, weight loss associated with AIDS, nausea and vomiting associated with cancer chemotherapy, muscle spasticity associated with multiple sclerosis, or intractable pain.[10]

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[10] Lee, P. R., Letter to Congressman Dan Hamburg, United States Public Health Service, July 13, 1994.

The National Institutes of Health reconsidered this issue in 1997[11] and has called for further research into alternate delivery systems for pure THC as well as research into the comparative efficacy of marijuana with newer available medicines which have added heightened efficacy to medication regimes. The summary also called into attention concern over pulmonary, neuro-, and immuno-toxicity of cannabis.

In 1997 the White House Office of National Drug Control Policy commissioned the National Academy of Sciences Institute of Medicine (IOM) to undertake an evaluation of the utility of marijuana and other cannabinoids[12] for medicinal applications. The study concluded (Table 3) that the challenge for future research will be to find cannabinoids which enhance therapeutic benefits while minimizing side effects such as intoxication and dysphoria. Delivery systems such as nasal sprays, metered dose inhalers, transdermal patches, and suppositories could be useful delivery systems for isolated or synthetic cannabinoids. The future for medicinal applications of cannabinoids and whether cannabinoids are equal or superior to existing medicines remains to be determined, but the IOM evaluation is particularly clear on the smoking of marijuana:

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[11] Workshop on the Medical Utility of Marijuana. Report to the Director, National Institutes of Health. http://www.nih.gov/news/pr/aug97/nih-08.htm.

[12] *Marijuana and Medicine: Assessing the Science Base* Janet E. Joy, Stanley J. Watson, Jr., and John A. Benson, Jr., Editors. Division of Neuroscience and Behavioral Health, Institute of Medicine. National Academy Press, Washington, D.C. 1999. Internet address www.nap.edu.

> If there is any future for marijuana as a medicine, it lies in its isolated components, the cannabinoids and their synthetic derivatives. Isolated cannabinoids will provide more reliable effects than crude plant mixtures. Therefore, the purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug, but such trials could be a first step towards the development of a rapid-onset, non-smoked cannabinoid delivery system.[13]

The following excerpts from the IOM report are instructive:

> The goal for drugs that treat nausea and vomiting produced by cancer chemotherapy is complete control (stop vomiting completely) or major control (two or fewer episodes of vomiting). . . . [14] A controlled double-blind study compared THC with a standard antiemetic drug, metoclopramide, in cancer patients who received cisplatin, the chemotherapeutic drug that causes vomiting in more than 99 percent of patients. . . . [15]

Results	Complete Control	Major Control
Metoclopramide	47 percent	73 percent
THC	13 percent	27 percent

> (Other study) results suggest that THC reduces chemotherapy-induced emesis. These studies also indicate that the degree of efficacy is not

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[13] IOM Report, p. 20.

[14] Ibid., p. 4.11.

[15] Ibid., p. 4.11-4.12.

high. . . .[16] As with the THC trials, nabilone and levonantradol (two synthetic analogues of THC) reduced emesis, but not as well as other available agents. . . .[17] A double-blind, cross-over, placebo controlled study compared THC pills to smoked marijuana in 20 cancer patients receiving a variety of chemotherapeutic drugs. Only 25 percent of patients achieved complete control of vomiting. . . .[18]

Preferred THC Pills	35 percent
Preferred Marijuana	20 percent
No Preference	45 percent

Although many marijuana users have claimed that smoked marijuana is a more effective antiemetic than oral THC, no controlled studies have yet been published that analyze this in sufficient detail to estimate the extent to which that is the case. . . .[19] *Major progress, generally not well-known to the public, in controlling chemotherapy-induced acute nausea and vomiting has been made since the 1970s* (emphasis added). Patients receiving the most difficult to control emetic agents now have no more than a 20-30 percent likelihood of experiencing acute emesis, whereas in the 1970s the likelihood was nearly 100 percent despite (then standard) antiemetics. . . .[20] Cannabinoids are not as effective as several other classes of agents. . . . As with cannabinoids, efficacy was apparent with

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[16] Ibid., p. 4.12.

[17] Ibid., p. 4.13.

[18] Ibid., p. 4.13.

[19] Ibid., p. 4.14.

[20] Ibid., p. 4.15.

smoked marijuana, but the degree of efficacy was no better than that seen with available antiemetic agents now considered to be marginally satisfactory. It is theoretically possible . . . that added to more effective regimens, THC might enhance control of emesis. . . . The critical issue is not whether marijuana or cannabinoid drugs might be superior to the new drugs, but rather whether there is a group of patients who might obtain added or better relief from marijuana or cannabinoid drugs. . . . [21] Most chemotherapy patients are unlikely to want to use marijuana or THC as an antiemetic. In 1998, there are more effective antiemetic agents available than were available earlier. By comparison, cannabinoids are only modest antiemetics. . . . However . . . cannabinoids might be effective in people who respond poorly to currently used antiemetic drugs, or cannabinoids might be more effective in combination with the new drugs than either are alone. . . . Therefore research should be pursued for patients whose nausea and vomiting is not completely controlled by standard antiemetics. . . . Antiemetic pills are given to cancer patients before chemotherapy begins and then afterwards. In those patients who nonetheless experience nausea and vomiting after chemotherapy, "an inhalation (but preferably not smoking) cannabinoid drug delivery system would be advantageous for treating chemotherapy-induced nausea."[22]

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[21] Ibid., p. 4. 16.

[22] Ibid., p. 4.17.

Marijuana adversely impacts concentration, motor coordination, and memory,[23] factors that must be considered in any discussion of providing this drug to patients suffering chronic diseases. The ability to perform complex tasks, such as flying,[24] is impaired even 24 hours after the acute intoxication phase. The association of marijuana use with trauma and intoxicated motor vehicle operation is also well established.[25] This is of central importance in an ambulatory environment where patients may smoke marijuana and then drive automobiles. Recent evaluations[26] of the effect of marijuana on driving determined that the combination of blood alcohol concentrations (BAC) of 0.07 and marijuana 100ug/kg gave effects similar to a BAC of 0.09. Blood alcohol concentrations of 0.07 and marijuana levels of 200ug/kg demonstrated effects similar to a BAC of 0.14 when measuring reaction time, on-road performance, and vehicle following. The study concluded, "Under marijuana's influence,

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[23] Murray, J. B., Marijuana's effects on human cognitive functions, psychomotor functions, and personality. *Journal of General Psychology.* 1986;113:23-55.

[24] Yesavage, J. A., Leirer, V. O., Denari, M., and Hollister, L. E., Carry-over effects of marijuana intoxication on aircraft pilot performance; a preliminary report. *Am. J. Psychiatry.* 1985;142:1325-1329.

[25] Gerostamoulos, J., and Drummer, O. H., Incidence of psychoactive cannabinoids in drivers killed in motor vehicle accidents. *Journal of Forensic Sciences.* 1993;38:649-656.

[26] National Highway Traffic Safety Administration. Marijuana and Alcohol Severely Impede Driving Performance. *Annals of Emergency Medicine* 2000:35;398-399. NHTSA study – National Highway Traffic Safety Administration. Marijuana Alcohol and Actual Driving Performance. DOT HS 808.939.

drivers have reduced capacity to avoid collisions if confronted with the sudden need for evasive action." A second related study found that a BAC of .05 combined with moderate marijuana produced a significant drop in the visual search frequency.

Positron scanning[27] of subjects' mean use of marijuana 17 times per week for the last 2 years found lower blood flow in a large region of the posterior cerebellum. Not only does this have implications on motor coordination and function, but also cognition, timing, processing sensory information, and attention.

Despite arguments of legalization advocates to the contrary, marijuana is a dependence-producing drug. Strangely, in the course of the rescheduling hearings, petitioners admitted that "marijuana has a high potential for abuse and that abuse of the marijuana plant may lead to severe psychological or physical dependence." These are points which they now deny. However, this dependence and associated "addictive" behaviors have been well described in the marijuana literature.[28] [29] [30]

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[27] Block, R. I., O'Leary, D. S., Hichwa, R. D., Augustinack, J. C., Boles-Ponto, L. L., Ghoneim, M. M., Arndt, S., Ehrhardt, J. C., Hurtig, R. H., Watkins, G. L., Hall, J. A., Nathan, P. E., Andreasen, N. C. Cerebellar hypoactivity in frequent marijuana users. *NeuroReport*. 2000;4:749-753.

[28] Compton, D. R., Dewey, W. L., and Martin, B. R., Cannabis dependence and tolerance production. *Advances in Alcohol and Substance Abuse*. 1990;9:129-147.

[29] Miller, N. S., and Gold, M. S., The diagnosis of marijuana (cannabis) dependence. *Journal of Substance Abuse Treatment*. 1989;6:183-192.

[30] Schwartz, R. H., Marijuana: an overview. *Pediatric clinics of North America*. 1987;34:305-317.

Marijuana dependence consists of both a physical dependence (tolerance and subsequent withdrawal) and a psychological dependence. Withdrawal from marijuana has been demonstrated in both animals[31] and humans.[32]

While the dependence producing properties of marijuana are probably a minimal issue for chemotherapy-associated nausea when medication is required sporadically, it is a major issue for the chronic daily use necessary for glaucoma, AIDS wasting syndrome, and other alleged chronic applications.

The respiratory difficulties associated with marijuana use preclude the inhaled route of administration as a medicine. Smoking marijuana is associated with higher concentrations of tar, carbon monoxide, and carcinogens than are found in cigarette smoking.[33] Marijuana adversely impairs some aspects of lung function and causes abnormalities in the respiratory cell lines from large airways to the alveoli.[34] [35] Marijuana smoke causes

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[31] Martin, B. R., The THC receptor and its antagonists. In: Nahas, G. G., Burks, T. F., eds. Drug Abuse in the Decade of the Brain. Amsterdam: IOS press. 1997:139-144.

[32] Duffy, A., Milin, R., Case Study: Withdrawal Syndrome in Adolescent Chronic Cannabis Users. *J. Am. Acad. Child Adolesc. Psychiatry.* 1996;35:1618-21.

[33] Wu, T. C., et al., Pulmonary hazards of smoking marijuana as compared with tobacco. *NEJM.* 1988;318:347-351.

[34] Tashkin, D. P., Shapiro, B. J., Lee, Y. E., and Harper, C. E., Subacute effects of heavy marijuana smoking on pulmonary function in healthy men. *NEJM.* 1976;294:125-129.

[35] Barbers, R. G., et al., Differential examination of bronchoalveolar lavage cells in tobacco cigarette and marijuana smokers. *Am. Rev. Respir. Dis.* 1987;135:1271.

inflammatory changes in the airways of young people that are similar to the effects of tobacco.[36] In addition to these cellular abnormalities and consequences, contaminants of marijuana smoke are known to include various pathogenic bacteria and fungi.[37] Those at particular risk for the development of disease and infection when these substances are inhaled are those users with impaired immunity.

One of the earliest findings in marijuana research was the effect on various immune functions, which is now evidenced by an inability to fight herpes infections and the discovery of a blunted response to therapy for genital warts during cannabis consumption.[38]

Abnormal immune function is, of course, the cornerstone of problems associated with AIDS. The use of chronic THC in smoked form for AIDS wasting not only exposes the patient to unnecessary pathogens, but also risks further immunosuppression. Evaluation of the effect of THC on NK-*k*B has suggested a possible effect on the HIV genome. A hallmark of the treatment for AIDS is *avoidance* of drug use, not extension or perpetuation of it.

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[36] Roth, M. D., Arora, A., Barsky, S. H., Kleerup, E. C., Simmons, M., Tashkin, D. P., Airway inflammation in young marijuana and tobacco smokers. *Am. J. Respir. Crit. Care Med.* 1998;157:928-937.

[37] Fleisher, M., Winawer, S. J., and Zauber, A. G., Aspergillosis and marijuana. *Annals of Internal Medicine.* 1991;115:578-579.

[38] Gross, G., Roussaki, A., Ikenberg, Drees N., Genital warts do not respond to systemic recombinant interferon alfa-2 treatment during cannabis consumption. *Dermatologica.* 1991; 183:203-207.

It should be clear that marijuana exposes the user to substantial health risks. In chronic use, or use in populations at high risk for infection and immune suppression, the risks are unacceptable.

Amici assert that in the interest of protecting seriously and terminally ill patients from unsafe and ineffective drugs, the safety and efficacy process of the FDA cannot be bypassed. Crude marijuana, an impure and toxic substance has no place in the medical armamentarium. It is no more reasonable to consider marijuana a medicine than it is to consider tobacco a medicine.

Coupled with the medical risk to patients, serious regulatory questions arise that have not been adequately dealt with by ballot initiatives. Those who propose medical uses, or who conduct research on the use of marijuana, have an ethical responsibility not to expose their subjects to unnecessary risks. Under current guidelines, crude marijuana is not a medicine, and allowing it as such would be a step backward to the times of potions and herbal remedies.

DIMINISHING PERCEPTION OF HARM INCREASES USE

Amici note the profound correlation in benchmark surveys of drug use, which show that the more people who believe a drug is harmful, the fewer people use that drug. Equally profound are the surveys' findings that the reverse is also true: the fewer people who believe a drug is harmful, the more people use that drug. These surveys show that perception of harm with respect to marijuana has been dropping off annually since the renewal of the

drive to legalize marijuana as medicine, which began in the early 1990s when legalization advocates first gained a significant increase in funding and began planning the state ballot initiative drive to legalize crude marijuana as medicine. The surveys are the Monitoring the Future Survey, which has tracked drug use among American high school students annually since 1975[39] and the National Household Survey on Drug Abuse, which has tracked drug use among Americans ages 12 and older annually or less frequently since 1972.[40]

The 1999 National Household Survey on Drug Abuse, released in October 2000, was conducted for SAMHSA by North Carolina's Research Triangle Institute.[41] For the first time in the history of this survey, the population sample was vastly increased (from an average of 15,000 to 75,000) in order to provide data about individual states, as well as about the nation as a whole. The state data reveals that those states which have passed medical marijuana laws have among the highest levels of past-month marijuana use, of past-month other drug use, of drug addiction, and of drug and alcohol addiction (Also see Table 4):

> **Drug Addiction** – Alaska and Nevada have the highest rates of drug addiction in the nation,

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[39] *Monitoring the Future*, National Institutes of Health, National Institute on Drug Abuse, available on the Internet at <www.monitoringthefuture.org>.

[40] *Summary of Findings from the 1999 National Household Survey on Drug Abuse*, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Rockville MD, 2000, pp 64-65, 74-75.

[41] Ibid.

California and Oregon have the 4th highest rates, the District of Columbia has the 5th highest rate, Washington has the 6th highest rate, Arizona and Colorado have the 7th highest rates, and Maine has the 12th highest rate.[42]

Drug Use – Alaska has the highest rate of past-month drug use in the nation, Nevada has the 3rd highest rate, Colorado has the 4th highest rate, Washington has the 8th highest rate, California has the 9th highest rate, Oregon has the 11th highest rate, the District of Columbia has the 12th highest rate, and Arizona and Maine have the 15th highest rate.[43]

Amici are concerned about protecting seriously and terminally ill patients from being exposed to an unapproved drug. In contrast, we have *no* objection to any medicines that may evolve from the cannabinoids, including Marinol, provided that they are approved as safe and effective by the Food and Drug Administration under current federal law.

Amici are also concerned that legalization advocates' efforts to confuse the public about the difference between crude marijuana and the cannabinoids that scientists are studying for possible use in medicine have contributed to the past decade's drop in the perception of marijuana's harm and that this has resulted in an increase in marijuana use, other drug use, and drug addiction.

Amici believe that it is therefore critically important that the Supreme Court uphold the supremacy of the

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[42] Ibid.

[43] Ibid.

federal FDA new drug approval laws and of the federal Controlled Substance Act and strike down California's Proposition 215 and the other state medical marijuana laws that violate these federal statutes.

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APPENDIX

TABLE 1

States That Have Passed Medical Marijuana Initiatives[44]

California
Proposition 21
The Compassionate Use Act of 1996

Arizona
Proposition 200
The Drug Medicalization, Prevention, and Control Act of 1996

Proposition 300
A 1998 initiative to reinstate certain provisions of Proposition 200

Alaska
A 1998 Act Relating to the Medical Use of Marijuana for Persons Suffering from Debilitating Medical Conditions

Colorado
Medical Use of Marijuana for Persons Suffering from Debilitating Medical Conditions
Passed in 1998, but invalidated by the Colorado Supreme Court for insufficient signatures.

Nevada
Medical Marijuana Initiative of 1998

Oregon
Oregon Medical Marijuana Act of 1998

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[44] National Families in Action A Guide To Drug-Related State Ballot Initiatives, Initiative-Index, www.national families.org/guide/initiative__index.html.

Washington
Initiative 692
Medical Use of Marijuana Act of 1998

District of Columbia
Initiative 59
Legalization of Marijuana for Medical Treatment Initiative of 1998
Different sponsors but assisted by Americans for Medical Rights

Maine
A 1999 Act to Permit the Medical Use of Marijuana

Colorado
Medical Use of Marijuana for Persons Suffering from Debilitating Medical Conditions Passed in 2000.

Nevada
Medical Marijuana Initiative of 2000
Second vote required to amend state constitution

TABLE 2

EXAMPLES OF NON-CANNABINOID MEDICATIONS AVAILABLE FOR NAUSEA ASSOCIATED WITH CANCER CHEMOTHERAPY

Serotonin Antagonists
- Ondansetron (Zofran)
- Granisetron (Kytril)
- Tropisetron (Navoban)
- Dolasetron

Phenothiazines:
- Prochlorperazine (Compazine)
- Chlorpromazine (Thorazine)
- Thiethylperazine (Torecan)
- Perphenazine (Trilafon)
- Promethazine (Phenergan)

Corticosteroids
Dexamethasone (Decadron)
Methylprednisolone (Medrol)

Anticholinergics
Scopolamine (Trans Derm Scop)

Butyrophenones
Droperidol (Inapsine)
Haloperidol (Haldol)
Domperidone (Motilium)

Benzodiazepines
Lorazepam (Ativan)
Alprazolam (Xanax)

Substituted Benzamides
Metoclopramide (Reglan)
Trimethobenzamide (Tigan)
Alizapride (Plitican)
Cisapride (Propulsid)

Antihistamines
Diphenhydramine (Benedryl)

TABLE 3

Institute of Medicine Recommendations[45]

Recommendation 1: Research should continue into the physiological effects of synthetic and plant-derived cannabinoids and the natural function of cannabinoids found in the body. Because different cannabinoids appear to have different effects, cannabinoid research should include, but not be restricted to, effects attributable to THC alone.

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[45] IOM Report, p. ES. 11.

Recommendation 2: Clinical trials of cannabinoid drugs for symptom management should be conducted with the goal of developing rapid-onset, reliable, and safe delivery systems.

Recommendation 3: Psychological effects of cannabinoids such as anxiety reduction and sedation, which can influence perceived medical benefits, should be evaluated in clinical trials.

Recommendation 4: Studies to define the individual health risks of smoking marijuana should be conducted, particularly among populations in which marijuana use is prevalent.

Recommendation 5: Clinical trials of marijuana use for medical purposes should be conducted under the following limited circumstances: trials should involve only short-term marijuana use (less than six months); be conducted in patients with conditions for which there is reasonable expectation of efficacy; be approved by institutional review boards; and collect data about efficacy.

Recommendation 6: Short-term use of smoked marijuana (less than six months) for patients with debilitating symptoms (such as intractable pain or vomiting) must meet the following conditions:

- failure of all approved medications to provide relief has been documented,
- the symptoms can reasonably be expected to be relieved by rapid-onset cannabinoid drugs,
- such treatment is administered under medical supervision in a manner that allows for assessment of treatment effectiveness, and

– involves an oversight strategy comparable to an institutional review board process that could provide guidance within 24 hours of a submission by a physician to provide marijuana to a patient for a specified use.

Note: Recommendations 5 and 6 are consistent with current FDA research guidelines. The IOM report cautions that "the purpose of clinical trials of smoked marijuana," using research-grade marijuana rather than street marijuana, "*would not be to develop marijuana as a licensed drug,* but such trials could be a first step towards the development of a rapid-onset, nonsmoked cannabinoid delivery system" (emphasis added.) See our footnote 13.

TABLE 4

1999 National Household Survey on Drug Abuse[46]

(Highlighted states have passed medical marijuana initiatives since 1996)

Percent Reporting Past-Year Drug Dependence

State	Ranking	Rate
Alaska	**1**	**2.8**
Nevada	**1**	**2.8**
New Mexico	2	2.7
Delaware	3	2.4
California	**4**	**2.3**
Oregon	**4**	**2.3**
District of Columbia	**5**	**2.2**
Washington	**6**	**2.1**
Rhode Island	6	2.1
Massachusetts	6	2.1
Arizona	**7**	**2.0**
Colorado	**7**	**2.0**
Utah	7	2.0
Vermont	7	2.0
Connecticut	8	1.9
Montana	8	1.9
Michigan	9	1.8
New Hampshire	9	1.8
New York	9	1.8
National Average		1.7
Kansas	10	1.7
Louisiana	10	1.7
Minnesota	10	1.7
Mississippi	10	1.7
New Jersey	10	1.7

Percent Reporting Past-Month Drug Use

State	Ranking	Rate
Alaska	**1**	**10.7**
Massachusetts	2	10.1
Nevada	**3**	**9.6**
Colorado	**4**	**9.3**
New Mexico	5	8.9
Rhode Island	6	8.7
Delaware	7	8.5
Washington	**8**	**8.4**
California	**9**	**8.3**
Michigan	10	8.0
Oregon	**11**	**7.7**
Montana	11	7.7
New Jersey	11	7.7
Connecticut	11	7.7
District of Columbia	**12**	**7.6**
Indiana	13	7.5
Wyoming	14	7.3
Arizona	**15**	**7.1**
Maine	**15**	**7.1**
Hawaii	15	7.1
New/ Hampshire	16	7.0
New York	16	7.0
Pennsylvania	16	7.0
Wisconsin	16	7.0
National Average		6.9

Wyoming	10	1.7
Illinois	11	1.6
Indiana	11	1.6
Maryland	11	1.6
Missouri	11	1.6
Ohio	11	1.6
Wisconsin	11	1.6
Maine	**12**	**1.5**
Idaho	12	1.5
Georgia	12	1.5
North Carolina	12	1.5
North Dakota	12	1.5
Oklahoma	12	1.5
Pennsylvania	12	1.5
Tennessee	12	1.5
Alabama	13	1.4
Arkansas	13	1.4
Hawaii	13	1.4
Nebraska	13	1.4
South Carolina	13	1.4
South Dakota	13	1.4
Texas	13	1.4
Florida	14	1.3
Kentucky	14	1.3
Virginia	15	1.3
Iowa	16	1.2
West Virginia	16	1.2
Illinois	17	6.9
Florida	18	6.8
Vermont	18	6.8
Minnesota	19	6.7
Missouri	20	6.6
Ohio	21	6.5
Idaho	22	6.4
North Carolina	23	6.3
Utah	24	6.2
Kentucky	25	6.0
South Dakota	25	6.0
Kansas	26	5.9
Georgia	27	5.8
Mississippi	27	5.8
Louisiana	28	5.7
Nebraska	29	5.6
Iowa	30	5.5
Tennessee	30	5.5
North Dakota	31	5.4
South Carolina	31	5.4
Texas	31	5.4
Maryland	32	5.3
Alabama	33	5.1
Oklahoma	33	5.1
West Virginia	33	5.1
Arkansas	34	5.0
Virginia	35	4.7

[46] National Families in Action: A Guide To Drug-Related State Ballot Initiatives, Percentage Reporting Past-Year Dependence, www. nationalfamilies.org/guide/dependence_use.html.